[57] **ABSTRACT**

A controlled release antihyperglycemic tablet that does not contain an expanding polymer and comprising a core containing the antihyperglycemic drug, a semipermeable membrane coating the core and at least one passageway in the membrane.

SUMMARY OF THE INVENTION

The foregoing objectives are met by a controlled release dosage form comprising:

(a) a core comprising:
  (i) an antihyperglycemic drug;
  (ii) optionally a binding agent; and
  (iii) optionally an absorption enhancer;

(b) a semipermeable membrane coating surrounding the core; and

(c) at least one passageway in the semipermeable membrane.

The binding agent may be any conventionally known pharmaceutically acceptable binder such as polyvinyl pyrrolidone, hydroxypropyl cellulose, hydroxyethyl cellulose, ethylcellulose, polymethacrylate, waxes and the like. Mixtures of the aforementioned binding agents may also be used. The preferred binding agents are water soluble such as polyvinyl pyrrolidone having a weight average molecular weight of 25,000 to 3,000,000. The binding agent comprises approximately about 0 to about 40% of the total weight of the core and preferably about 3% to about 15% of the total weight of the core. Col 3

pharmaceutically acceptable water soluble polymer and the absorption enhancer is preferably formed by wet granulating the core ingredients and compressing the granules with the addition of a lubricant into a tablet on a rotary press. The core may also be formed by dry granulating the core ingredients and compressing the granules with the addition of a lubricant into tablets or by direct compression. Col. 4.

In an alternative embodiment, the dosage form of the present invention may also comprise an effective amount of the antihyperglycemic drug that is available for immediate release. The effective amount of antihyperglycemic drug for immediate release may be coated onto the semipermeable membrane of the dosage form or it may be incorporated into the semipermeable membrane.

In a preferred embodiment the dosage form will have the following composition:

	Preferred	Most Preferred
CORE:		
drug	50–98%	75–95%
binder	0–40%	3–15%
absorption enhancer	0–20%	2–10%
COATING:		
semipermeable polymer	50–99%	75–95%
flux enhancer	0–40%	2–20%
plasticizer	0–25%	2–15%

Col. 5

In making the rejection, the Examiner contended only that:

> Cheng discloses a controlled release oral tablet comprising from 75-95% drug and up to about 40% waxes (see column 3, lines 34-49; and column 5, lines 30-36). The tablet provides both, immediate release and controlled release (see column 5, lines 22-26). The tablet further comprises fatty acid, surfactant (flow aid), and chelating agent (column 3, lines 51-60), and can further be coated with a semipermeable membrane comprises cellulose derivatives polymer (see column 4, lines 11-44). Cheng also discloses the tablet is prepared by compression (see column 6, lines 35-41).

(Part of Paper No./ Mail Date 05242005 at 4.)

As is well settled, anticipation requires "identity of invention." Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim.

Furthermore, in a §102(b) rejection there must be no difference between what is claimed and what is disclosed in the applied reference. Moreover, it is incumbent upon the Examiner to ***identify wherein each and every facet*** of the claimed invention is disclosed in the applied reference." The Examiner is required to point to the disclosure in the reference "***by page and line***" upon which the claim allegedly reads.

The rejection fails to identify where in Cheng each and every element of the rejected claims are shown. For example, the rejection fails to state where the affirmatively required "powdered wax" is disclosed. That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

Even further, the rejection does not point out where there is a disclosure of the required powdered wax in a swallowable immediate release tablet and a swallowable immediate release tablet meeting the USP dissolution specifications for immediate release tablets containing said active ingredient. Nor is it believed that the Examiner could make such a showing. For this additional reason, the rejection is improper and should be withdrawn.

As to claim 5, the Examiner failed to state where the affirmatively required disclosure of a "tablet [that] is substantially free of water-soluble, non-saccharide polymeric binders" is to be found in Harbit. That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

As to claim 6, the Examiner failed to state where the affirmatively required disclosure of a "tablet [that] is substantially free of hydrated polymers" is to be found in Harbit. That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

Claims 1, 2, 4-6, 10-12,and 15 were rejected under 35 USC §102(e) as anticipated by Robinson, US Patent No. 6,270,790 ("Robinson"). (Part of Paper No./ Mail Date 05242005 at 4.)

For the reasons set forth below, the rejection, respectfully is traversed.

Robinson discloses

(57) **ABSTRACT**

The present invention relates to a compressed, chewable tablet containing at least one active ingredient, a water-disintegratable, compressible carbohydrate and a binder. These components are dry blended and compressed into convex-shaped tablet having a hardness of about 2 to about 11 kp/cm^2 and friability less than 1%.

The compressed, chewable tablets of the present invention comprise at least one active ingredient, a water-disintegratable, compressible carbohydrate, and a binder. These ingredients are dry blended and then compressed into a convex-shaped tablet having a hardness of about 2 to about 11, preferably about 5 to about 8.5, kp/cm^2. Tablet friability is also preferably less than 1%. Col. 2.

The binder in the present invention is used to add cohesiveness to the formulation, thereby providing the necessary bonding to form a cohesive mass or compact upon compression. These binders are conventionally used in direct compression tablets and are described in Lieberman et al., *Pharmaceutical Dosage Forms*, 2 Ed., Vol. 1, pp. 209–214 (1990), which is hereby incorporated by reference. Preferred binders include cellulose, cellulosic derivatives, polyvinyl pyrrolidone, starch, modified starch, and mixtures thereof, and, in particular, microcrystalline cellulose available from FMC Corp. under the trademark AVICEL® PH 101.

The tablets of the present invention are used to orally administer a wide variety of active ingredients. Suitable active ingredients include pharmaceuticals, minerals, vitamins and other nutraceuticals. Suitable pharmaceuticals include analgesics, decongestants, expectorants, antitussives, antihistamines, gastrointestinal agents, diuretics, bronchodilators, sleep-inducing agents and mixtures thereof. Preferred pharmaceuticals include acetaminophen, ibuprofen, flurbiprofen, naproxen, aspirin, pseudoephedrine, phenylpropanolamine, chlorpheniramine maleate, dextromethorphan, diphenhydramine, famotidine, loperamide, ranitidine, cimetidine, astemizole, terfenadine, terfenadine carboxylate, cetirizine, mixtures thereof and pharmaceutically acceptable salts thereof. Col. 2.

masking composition, either by film coating or by another process such as coaccervation. The tablet may provide for immediate or sustained release of the active. Col. 3.

The tablet may also contain ingredients other than the coated particles, carbohydrate and binder. The additional ingredients include sweeteners, such as aspartame, acesulfame potassium, sucralose and saccharin; and lubricants, such as magnesium stearate, stearic acid, talc, and waxes. The dosage form may also incorporate pharmaceutical acceptable adjuvants. Such adjuvants, include, for example, preservatives, flavors, antioxidants, surfactants, and/or colors. Col. 5.

In making the rejection, the Examiner contended only that:

> Robinson discloses a direct compressed tablet comprising up to about 60% by weight of at least one active ingredient, waxes and other excipients (see abstract, and column 5, lines 14-21). The active ingredient includes ibuprofen, acetaminophen, naproxen, aspirin, cetirizine, and mixtures thereof (column 2, lines 54-67). The tablet is suitable for immediate release and/or sustained release (column 3, lines 30-31).

(Part of Paper No./ Mail Date 05242005 at 4.)

As is well settled, anticipation requires "identity of invention." Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim.

Furthermore, in a §102(e) rejection there must be no difference between what is claimed and what is disclosed in the applied reference. Moreover, it is incumbent upon the Examiner to ***identify wherein each and every facet*** of the claimed invention is disclosed in the applied reference." The Examiner is required to point to the disclosure in the reference "***by page and line***" upon which the claim allegedly reads.

The rejection fails to identify where in Robinson each and every element of the rejected claims are shown. For example, the rejection fails to state where the affirmatively required "powdered wax" is disclosed. It is submitted that a disclosure of "wax" is not a disclosure of "powdered wax." That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

Even further, the rejection does not point out where there is a disclosure of the required powdered wax in a swallowable immediate release tablet and a swallowable immediate release tablet meeting the USP dissolution specifications for immediate release tablets containing said active ingredient. Nor is it believed that the Examiner could make such a showing. For this additional reason, the rejection is improper and should be withdrawn.

As to claim 5, the Examiner failed to state where the affirmatively required disclosure of a "tablet [that] is substantially free of water-soluble, non-saccharide polymeric binders" is to be found in Harbit.' That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

As to claim 6,the Examiner failed to state where the affirmatively required disclosure of a "tablet [that] is substantially free of hydrated polymers" is to be found in Harbit. That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

Claims 1, 4-8, and 10-14 were rejected under 35 USC §102(e) as anticipated by Smith, US Patent No. 6,194,000 ("Smith"). (Part of Paper No./ Mail Date 05242005 at 4.)

For the reasons set forth below, the rejection, respectfully is traversed.

Smith discloses

(57) **ABSTRACT**

Disclosed is a method for the therapeutic treatment of pain related to wind up in a human or animal. The method of the invention is practiced by administering to the subject an effective amount of an analgesic pharmaceutical composition which includes a NMDA receptor antagonist in an immediate release form combined with an NMDA receptor antagonist in a sustained release form. The immediate release form and sustained release form are present in sufficient amounts to diminish or abolish wind up.

The formulation may include sufficient NMDA receptor antagonist to provide from about 1–5000 mg/day, typically 1–1000 mg/day and preferably about 100–800 mg/day of the active ingredient. The composition includes an NMDA receptor antagonist in an immediate release form in association with a NMDA receptor antagonist in a controlled release form. The composition may include an amount of NMDA receptor antagonist in the immediate release form of approximately 5% to 90% of the total NMDA receptor antagonist, preferably 10% to 60%. An immediate release NMDA receptor antagonist content of about 15% to 50% is particularly preferred. The controlled release form of the NMDA receptor antagonist may constitute the remainder of the active ingredients.

The composition of the invention may be in a form suitable for oral or rectal administration or for administration by transdermal, intravenous, intramuscular, subcutaneous, intrathecal, epidural or intracerebroventricular means.

The composition of the invention may or may not be in a single dosage form. Preferably the composition is in a single dose form.

The composition may be formulated as an oral dosage form such as a tablet, capsule, a liquid, powder, granule or suspension, an injectable solution, a suppository, implant or transdermal patch.

Col. 2.

A suitable immediate release (IR) form of the NMDA receptor antagonist may simply be particles of the antagonist or particles of the antagonist admixed with soluble components for example, sugars (eg sucrose, lactose, fructose, mannitol etc.), polymers (eg polyethylene glycol, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, etc), surfactants (sodium lauryl sulphate, chremophor, tweens, spans, pluronics, and the like), insoluble components (microcrystalline cellulose, $Ca_3(PO_4)_2$, talc, fumed silica, i.e. aerosil® and the like), coating material (examples of suitable coating materials are polyethylene glycol, hydroxypropyl methyl cellulose, wax, fatty acids, etc.), dispersions in suitable material (examples are wax, polymers, pharmaceutically acceptable oils, soluble agents etc) or combinations of the above. These mixtures may be prepared by blending, mixing, dissolution and evaporation, or by using suspensions etc. These mixtures may be deposited on inert cores, wet massed and extruded, granulated, spray dried, etc. These mixtures or processed mixtures may be used in suspensions, filled into capsules, tabletted, filled into sachets, used in confectionery and so on. Col. 3.

In making the rejection, the Examiner contended that:

Smith discloses an analgesic composition comprising immediate and controlled release forms (see abstract). The immediate release comprises up to 90% of the analgesic agent, polyethylene glycol, waxes, and other carriers (column 2, lines 39-50; and column 3, lines 29-51). The dosage form provides from about 1-5000 mg/day of the analgesic agent (ID). The composition is in for oral administration in tablet or capsule or granule form (column 2, lines 55-67). Suitable coating to provide sustained release comprises cellulose derivatives polymer (column 4, lines 26-45).

(Part of Paper No./ Mail Date 05242005 at 4-5.)

As is well settled, anticipation requires "identity of invention." Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim.

Furthermore, in a §102(e) rejection there must be no difference between what is claimed and what is disclosed in the applied reference. Moreover, it is incumbent upon the Examiner to ***identify wherein each and every facet*** of the claimed invention is

disclosed in the applied reference." The Examiner is required to point to the disclosure in the reference "***by page and line***" upon which the claim allegedly reads.

The rejection fails to identify where in Smith each and every element of the rejected claims are shown. For example, the rejection fails to state where the affirmatively required "powdered wax" is disclosed. It is submitted that a disclosure of "wax" is not a disclosure of "powdered wax." That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

Even further, the rejection does not point out where there is a disclosure of the required powdered wax in a swallowable immediate release tablet and a swallowable immediate release tablet meeting the USP dissolution specifications for immediate release tablets containing said active ingredient. Nor is it believed that the Examiner could make such a showing. For this additional reason, the rejection is improper and should be withdrawn.

As to claim 5, the Examiner failed to state where the affirmatively required disclosure of a "tablet [that] is substantially free of water-soluble, non-saccharide polymeric binders" is to be found in Harbit. That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

As to claim 6, the Examiner failed to state where the affirmatively required disclosure of a "tablet [that] is substantially free of hydrated polymers" is to be found in Harbit. That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

Obviousness Rejections

Claims 1-20 were rejected under 35 USC §103(a) as being unpatentable over Cheng, or Robinson, or Smith, or Harbit in view of WO 01/21155 A1 ("Remon"). (Part of Paper No./ Mail Date 05242005 at 5.)

For the reasons set forth below, the rejection, respectfully is traversed.

The disclosures of Cheng, Robinson, Smith, and Harbit set forth above are incorporated herein by reference.

Remon discloses

(57) Abstract: Biologically inactive cushioning beads comprise at least one compressible cushioning component consisting essentially of a microcrystalline hydrocarbon wax or a natural wax, the said wax being at least 30 % by weight of the biologically inactive cushioning beads. Such beads are useful for making solid shaped articles containing biologically active ingredients by compression.

The formulation of a solid oral dosage form, whether tablet or capsule, which disintegrates rapidly in water to form an instantaneous homogenous suspension of adequate viscosity to be swallowed could circumvent the problems of administering large dosages without premature release from controlled-release particles while providing a ready measured dose. The key to the development of such a dosage form is a rapidly disintegrating tablet which disperses to form a viscous suspension. A delay in the development of a viscous gel is essential for achieving disintegration of the tablet. On the

p. 1

properties.

The ideal solid oral dosage form should contain a swellable material which is able to increase viscosity on contact with water, at least one biologically active ingredient for immediate or sustained release delivery of the biologically active ingredient, and a filler conferring compactibility and the capability to disintegrate quickly. The inclusion of a viscosity increasing agent as a fine powder in the tablet matrix without any processing would interfere with disintegration and result in the formation of a voluminous hydrophilic mass which is impossible to disperse. Thus, it is necessary to incorporate such an agent into the tablet as granules or spheres so that the disintegration process occurs before the viscosity increase.

p. 2

The present invention may provide biologically inactive cushioning beads comprising at least one compressible cushioning component consisting essentially of a microcrystalline hydrocarbon wax or a natural wax, the said wax being at least about 30% by weight of the biologically inactive cushioning beads and which are useful for making solid shaped articles containing biologically active ingredients by compression.

p. 10

For the performance of the present invention, it is preferable to use a microcrystalline hydrocarbon wax having a congealing point between about 50°C and 90°C and which is water-insoluble. The microcrystalline hydrocarbon wax usually comprises a mixture of linear (normal) and branched (iso) hydrocarbons, According to a preferred embodiment of the present invention, the said mixture comprises from about 30 to about 90% by weight of linear hydrocarbons and from about 10 to about 70% by weight of branched hydrocarbons. Also preferably, the microcrystalline hydrocarbon wax

p. 12

flavoring agent (e.g. vanillin), buffering agent, filler, disintegrating agent and/or swellable material. Preferably the cushioning beads of the present invention include at least about 5% by weight of at least one such biologically inactive pharmaceutically acceptable additive (excipient) distributed throughout the beads, for instance in the form of an intimate mixture of wax and excipient. A disintegrating agent is especially useful as an excipient for providing quick-disintegrating characteristics when making a solid shaped article containing biologically active ingredients by compression.

p. 15

In making the rejection, the Examiner incorporated the assertions set forth in the anticipation rejections above concerning Cheng or Robinson, or Smith, or Harbit into the instant rejection. The Examiner acknowledged, however, that "the references are silenced as to the teach of the same wax. (Part of Paper No./ Mail Date 05242005 at 5.)

To fill the acknowledged gap, the Examiner relied upon Remon. The Examiner contended that

- "Remon teaches a rapidly disintegrating tablet comprising an active agent and wax particles." ((Part of Paper No./ Mail Date 05242005 at 5.)
- The wax is a microcrystalline wax or a natural wax. (*Id.*)
- The "composition further contains disintegrants, swellable materials as well as other fillers." (*Id.*)
- The wax particles have an average particle size of 0.5 to 2.0 mm. (*Id.*)
- The actives are chosen from a wide variety of known pharmaceutical agents. (*Id.* at 4-5)
- The composition includes a film coating. (*Id.* at 5)
- The tablets are produced by compression. (*Id.*)
- The tablets are rapid disintegration tablets. (*Id.*)

The Examiner admitted that "Remon does not refer to wax particles as powder." To fill this acknowledged gap, the Examiner looked to a dictionary definition for powder. Based on that definition the Examiner reasoned that since the claims of the captioned application "do not recite a particle size for the wax particles, the instant claims are deemed anticipated by Remon." (*Id.*) The Examiner concluded that "it would have been obvious to one of ordinary skill in the art to modify the composition of Cheng, or Robinson, or Smtih using the wax in view of the teaching of Remon, because Remon teaches tablet compression suitable in pharmaceutical art." (*Id.*)

At the outset, the Examiner concluded that "the instant claims are deemed anticipated by Remon." (Part of Paper No./ Mail Date 05242005 at 6.) It is not clear

why this statement is included to support an obviousness rejection. Further, there was no anticipation rejection based on Remon. Perhaps the Examiner overlooked this language when relying on Remon from an earlier paper. Regardless, this statement makes the instant rejection unclear and, it is submitted, difficult to respond to. Nonetheless, in order to expedite prosecution on merits, the following response is being provided as if the statement were not present.

While the Examiner stated that Herbit formed the basis for an obviousness rejection, there is no conclusion or reasoning of obviousness based on Herbit provided by the Examiner. For this reason the rejection based on Herbit is improper and should be withdrawn.

Robinson, as admitted by the Examiner, constitutes prior art under 35 USC § 102(e). (Part of Paper No./ Mail Date 05242005 at 4.) Robinson has an effective filing date of August 18, 1998 and McNeil-PPC, Inc. is the assignee of Robinson.

The captioned application has a filing date of September 28, 2001. McNeil-PPC, Inc. is the assignee of the captioned application.

It is submitted that Robinson and the captioned application were, at the time the instant invention was made, owned by or subject to an obligation of assignment to the same person. 1241 OG 96 (Dec. 26, 2000). Because the captioned application was filed on or after November 29,1999, the captioned application qualifies for the benefit of the §103(c)/102(e) exclusion of common assignee-type prior art. Therefore, Robinson is not available as reference to reject the captioned application for obviousness. For this reason, the rejection is improper and should be withdrawn.

For a *prima facie* case of obviousness to be established, the teachings from the prior art itself must appear to have suggested the claimed subject matter to one of ordinary skill in the art. The mere fact that the prior art could be modified as proposed by the Examiner is not sufficient to establish a *prima facie* case of obviousness.

The Examiner asserted that Remon discloses "**wax particles**." (Part of Paper No./ Mail Date 05242005 at 5.) However, it is not seen where Remon discloses wax particles. The following are the citations relied on by the Examiner for this factual assertion:

The present invention may provide biologically inactive cushioning beads comprising at least one compressible cushioning component consisting essentially of a microcrystalline hydrocarbon wax or a natural wax, the said wax being at least about 30% by weight of the biologically inactive cushioning beads and which are useful for making solid shaped articles containing biologically active ingredients by compression.

p. 10, lns. 14-18

by the extrudate density and granulating fluid content.

In view of their properties, the cushioning beads such as disclosed above are useful for, among others, producing by compaction a wide range of solid shaped articles of biologically or therapeutically active ingredients. Thus a second object of the present invention consists of a solid shaped article containing biologically active ingredient-loaded beads and further comprising biologically inactive cushioning beads comprising at least one compressible cushioning component consisting essentially of a microcrystalline hydrocarbon wax or a natural wax, the said wax being at least about 30% by weight of the biologically inactive cushioning beads.

The term "solid shaped article " as used herein means any article being in a hard solid state at temperatures not exceeding about 60°C and having a definite geometrical shape, such as for instance ordinary tablets, effervescent tablets, multilayer tablets, sustained-release tablets, pills, lozenges and other compressed dosage forms.

and p. 19, lns. 10-21.

However, it is not seen where even the term "particle" is used in these passages Nor is it seen where in Remon the "wax particle" is used. The Examiner is asked to make a showing where this term is used in Remon in the next paper issued in the captioned application.

Further, the Examiner opines that "the average size of the wax particles is from 0.5 to 2.0 mm." The following is the passage at page 18, lines 7-18, relied on by the Examiner for this factual assertion:

> The cushioning beads of the present invention preferably have an average particle size of about 0.5 to about 2.0 mm and most preferably from 0.75 to 1.25 mm. They can be produced by a number of different techniques such as high-shear mixing, extrusion, extrusion-spheronization or by other means, as long as the said technique results in free-flowing beads, not granules, having a narrow size distribution range. The preferred production process involves high-shear mixing of the microcrystalline hydrocarbon wax or natural wax of similar characteristics and the optional additives (excipients) in view to achieve the average particle size mentioned above. As used herein, the term "high-shear mixing " means mixing the beads components at a high shear rate as is readily known to those skilled in the art. When high-shear mixing is used as the production technique, the temperature of mixing and should preferably be in the range of about 45 to about 60°C, most preferably in the range of about 50 to about 55°C.

As is seen above, the passage is directed to "cushioning beads." According to Remon, the cushioning beads are made of additional materials besides wax. The following passage from page 15. lines 9-20, support this fact.

> In addition to the microcrystalline hydrocarbon wax or natural wax of substantially similar characteristics, the cushioning beads of the present invention may include up to about 70% by weight of another compressible biologically inactive cushioning component or at least a biologically inactive but pharmaceutically acceptable additive (excipient) such as colorant, sweetener (e.g. sucrose, mannitol, saccharin and aspartame), flavoring agent (e.g. vanillin), buffering agent, filler, disintegrating agent and/or swellable material. Preferably the cushioning beads of the present invention include at least about 5% by weight of at least one such biologically inactive pharmaceutically acceptable additive (excipient) distributed throughout the beads, for instance in the form of an intimate mixture of wax and excipient. A disintegrating agent is especially useful as an excipient for providing quick-disintegrating characteristics when making a solid shaped article containing biologically active ingredients by compression.

Therefore, "the average size of the wax particles" relied on by the Examiner is actually for the cushioning beads, not for individual wax particles. In addition, the cushioning beads can include other ingredients, which could influence the size of the cushioning beads. For this reason, the rejection improper and should be withdrawn.

Additionally, the Examiner continues to rely on extrinsic evidence for what the term "powder" means. It is submitted that such definition is not needed to understand the

claimed invention in view of the documents cited by the Examiner. First, it is not seen where any of the primary documents in the instant rejections cite the term "powder" in conjunction with term "wax." Nor is it believed Remon closes this gap. While the Examiner continues to assert that Remon discloses wax "powder" without expressly using the term by using extrinsic evidence, it is respectfully submitted that if Remon were to have intended to do so, Remon would have used the term. In support of this, Remon uses the term "powder particles" in the following passage

> microencapsulation and it is also possible to formulate the active ingredient into
> the non-coated components.
>
> Conventionally in the art, granules are aggregates formed by agglomeration (also referred to as granulation) of powder particles through the sticking together of individual feed material components. Although the said individual components may not segregate,

(page 6.)

Therefore, it is submitted that if Remon did recite "wax particles", which is denied, Remon would not have intended to include "powder particles" is such a statement, if that was what was intended. For this additional reason, the rejection is improper and should be withdrawn.

Finally, the Examiner is invited to call the applicants' undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason, the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP §707.07(j) or in making constructive suggestions pursuant to MPEP §706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Respectfully submitted,

By:/Timothy E. Tracy, Reg. No. 39,401/
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